Supplement to

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FDA PROPOSED REGULATIONS UNDER FOOD ADDITIVE LAW

The Food and Drug Administration published in the Federal Register of December 9 the text of regulations it proposes to issue under the 1958 Food Additives amendment to the Food and Drug Act.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

PROPOSED DEFINITIONS AND PROCEDURAL AND INTREPRETATIVE REGULATIONS

The Commissioner of Food and Drugs, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 402, 409, 701; 72 Stat. 1784, 1785 et seq.; 52 Stat. 1055, as amended, 70 Stat. 919, 72 Stat. 948; 21 U. S. C. 321, 342, 348, 371) and pursuant to authority delegated to him by the Secretary of Health, Education, and Welfare, proposes the promulgation of the following regulations with respect to food additives, and hereby offers an opportunity to all interested persons to present their views in writing to the Hearing Clerk, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington 25, D. C., within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Comments may be accompanied by a memorandum or brief, and it is requested that all comments be submitted in quintuplicate.

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SUBPART A—DEFINITIONS AND PROCEDURAL AND INTERPRETATIVE REGULATIONS

§ 121.1 *Definitions and interpretations.* (a) "Secretary" means the Secretary of Health, Education, and Welfare.

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended; 21 U. S. C. 301–392).

(e) "Food additive" includes all substances the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. "Affecting the characteristics of food" does not include physical effects, such as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) "Common use in food" refers to usage of a substance by consumers, regardless of the number of manufacturers who may produce it.

(g) "Scientific procedures" include not only original animal, analytical, and other scientific studies, but also a compilation of reliable information drawn from the scientific literature.

(h) "Safe" means that there is convincing evidence that no harm can come from the intended use of the food additive.

§ 121.2 *Pesticide chemicals in processed foods.* When pesticide chemical

residues occur in processed foods due to the use of raw agricultural commodities that bore or contained lawful pesticide residues, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the act. For example, if fruit bearing a residue of 7 parts per million of DDT, permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part.

§ 121.3 *Substances added to food which are not generally recognized as safe.* (a) In general, any substance added to food which has no history of common use as a food ingredient should be regarded as a substance that is not generally recognized as safe for its intended food use, for the purpose of sections 201 (s) and 402 (a) (2) (C) of the act, unless it has been scientifically tested and shown to be safe.

(b) Section 121.[illegible] contains a partial list of substances that are generally recognized among experts qualified by scientific training and experience to evaluate the safety of such substances as ingredients in food as safe for such use under the conditions set forth in that section. No substance will be removed from this list, nor will the permitted conditions of use be modified, without prior notice and a statement of the reasons for the action.

(c) Substances other than those listed in § 121.[illegible] for which prior sanction under the Federal Food, Drug, and Cosmetic Act has been given, are not listed. Upon written request, setting forth the specific product and a specific usage, the Commissioner will advise interested persons whether such use of such product has been sanctioned. Food additives sanctioned for use in foods for which standards of identity have been prescribed are listed in the standards. No prior sanction will be withdrawn or modified without prior notice and a statement of the reasons for the action.

(d) The Commissioner, upon written request, specifying the intended conditions of use and other pertinent information about a substance, will advise an interested person whether in his opinion the substance is a food additive.

(e) The training and experience necessary to qualify experts to evaluate the safety of food additives, for the purposes of section 201 (s) of the act, are essentially sufficient training and experience in biology, medicine, physiology, toxicology, pharmacology, veterinary medicine, or other appropriate science to recognize and to evaluate the behavior and effects of chemical substances in the diet of man and of animals.

§ 121.4 *Tolerances for related food additives.* (a) Food additives that cause related pharmacological effects will be regarded, in the absence of evidence to the contrary, as having additive toxic effects.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present, or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.

(2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(3) Add the percentages so obtained for all residues present.

(4) The sum of the percentages shall not exceed 100 percent.

§ 121.5 *Generally recognized safety factors to be considered.* In accordance with section 409 (c) (5) (C) of the act, the following generally recognized safety factors will be applied in determining whether a proposed use of a food additive will be safe for its intended uses: Except when the circumstances of the particular case require different treatment, a safety ratio based on animal-experiment data of 100 to 1 will be applied; that is, a food additive will not be granted a tolerance that will exceed $\frac{1}{100}$ of the maximum amount demonstrated to be without harm to experimental animals.

§ 121.6 *General principles for the evaluation of the safety of food additives.* (a) Unless evidence is available establishing that a different method and procedure will give equally or more reliable results, the Commissioner in reaching a decision on any petition filed under section 409 of the act will apply the applicable criteria for establishing the safety of food additives as outlined by the Food Protection Committee of the National Research Council in its publication entitled "Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods" (January 1957 Edition). For the purposes of this section, the criteria set forth in the above-referenced publication for the evaluation of intentional additives in food will apply equally to any substance that may properly be classified within the meaning of that term as it is defined in section 201 (s) of the act.

(b) Upon written request describing the proposed use of an additive and the proposed experiment to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive, whether he believes an experimental plan that is not in accord with the general guides of the pamphlet described in paragraph (a) of this section, will furnish data adequate for an evaluation of the safety of the additives.

§ 121.7 *Food additives for which new-drug applications are required.* (a) A substance that is a new drug within the meaning of section 201 (p) of the act may also be a food additive within the meaning of section 201 (s) by reason of the fact that its intended use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of a food. Any new drug that is intended for administration to a food-producing animal will also be evaluated under section 409 and a regulation issued where necessary. Where a substance is both a new drug and a food additive, the submission of a new-drug application in accordance with the regulations appearing in Part 130 of this Chapter will also be construed as a petition for the establishment of a regulation for the use of the substance as a food additive. A new-drug application will not be permitted to become effective for a use that results in the substance becoming a food additive until a regulation is established under section 409 of the act. The new-drug application and the establishment of a regulation respecting the food additive use will be acted upon simultaneously.

(b) With respect to those uses of a new drug that result in its becoming a food additive, the provisions of the regulations in this part shall apply concerning the procedure to be followed in establishing a food-additive regulation. Upon determination that a new-drug application contains a petition for the establishment of a food-additive regulation, the New Drug Branch of the Food and Drug Administration shall so notify the applicant prior to the effective date of the application, and shall inform him that his application with respect to the uses of the new drug which result in its becoming a food additive will be processed under the regulations in this part. Upon the issuance of the food-additive regulation, the New Drug Branch will notify the applicant that his application is effective to the extent allowed by the regulation. In the event the proceeding for the food-additive regulation results in the denial of a regulation allowing the use of the new drug as a food additive, the applicant shall be notified that the denial of his new-drug application is final with respect to the use of the new drug for uses resulting in its becoming a food additive.

§ 121.8 *Food additives proposed for use in foods for which definitions and standards of identity have been prescribed.* (a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409 (b) (5) of the act requires that the Secretary publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(c) A regulation will not be issued allowing the use of a food additive in a food for which a definition and standard of identity is established, unless the evidence demonstrates that the use of such food additive in the standardized food will promote honesty and fair dealing in the interest of consumers.

§§ 121.9–129.50 [Reserved.]

§ 121.51 *Petitions proposing regulations for food additives.* (a) Petitions to be filed with the Commissioner under the provisions of section 409 (b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post-office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner ----------
Post-office address ----------
Date ----------
Name of food additive and proposed use ----

FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington 25, D. C.

DEAR SIRS:

The undersigned, ----------, submits this petition pursuant to section 409 (b) (1) of the Federal Food, Drug, and Cosmetic Act with respect to the ----------
---
(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, or a statement that such information is not available and why it is not.

[When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

[If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

[If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

[If the food additive is one that is likely to be unstable, the petition shall include stability data, and, if needed to preserve the identity, strength, quality, and purity of the additive, an expiration date that will be employed.]

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food.

[Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.

[If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.]

C. Data establishing that the food additive will have the intended physical or other technical effect and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. The results of tests by practicable methods to determine the amount of the food additive in the finished food and of any substance formed in or on food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by various laboratories.

E. Full reports of investigations made with respect to the safety of the food additive.

[A petition may be regarded as incomplete unless it includes full reports of adequate tests by all methods reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.]

F. Proposed tolerances for the food additive, if tolerances are required in order to insure its safety.

G. If submitting petition to modify an existing regulation issued pursuant to section 409 (c) (1) (A) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. It is understood that all representations in the petition regarding the name, composition, manufacturing methods, controls, and labeling will apply to the food additive when it is actually produced and marketed, until an effective supplement to the petition provides for a change in the food additive.

Yours very truly,
Petitioner ----------
By ----------
(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed, and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if he obtains the manufacturer's written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner.

(g) A petition shall not be accepted for filing if any of the data prescribed by section 409 (b) (2) of the act are lacking or are not set forth so as to be readily understood.

(h) Data in a petition will be held confidential and not revealed unless it is necessary to do so in administrative or

judicial proceedings under section 409 of the act.

(i) (1) Within 15 days after receipt the Commissioner will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of notification becomes the date of filing for the purposes of section 409 (b) (5) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified, and date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing.

(2) The Commissioner will publish in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of filing, the name of petitioner, and a brief summary of the petition in general terms.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for the production of the food additive, or a sample of the food additive, or articles used as components thereof, or of the food in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used. The date used for computing the 90-day limit for the purposes of section 409 (c) (2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample requested is not submitted within 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

(k) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409 (c) (2) of the act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(l) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 121.52 *Withdrawal of petitions without prejudice.* In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

§ 121.53 *Substantive amendments to petitions.* After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date and the time limitation will begin to run anew.

§ 121.54 *Effective date.* A regulation published in accordance with § 121.7 (b) or § 121.72 shall become effective upon publication in the FEDERAL REGISTER.

§ 121.55 *Objections to regulations and requests for hearings.* (a) Objections to an order promulgated pursuant to section 409 (f) (1) of the act shall be submitted in quintuplicate to the Hearing Clerk of the Department at the address specified in such order. Each objection to a provision of the regulation shall be separately numbered.

(b) A statement of objections shall not be accepted for filing if:

(1) It is filed more than 30 days after the date of publication of the order in the FEDERAL REGISTER.

(2) It fails to establish that the objector will be adversely affected by the regulation.

(3) It does not specify with particularity the provisions of the regulation to which objection is taken.

(4) It does not state reasonable grounds for each objection raised. Grounds that it is reasonable to conclude are capable of being established by reliable evidence at the hearing, and which if proved would call for changing the provisions specified in the objections, will be deemed reasonable grounds.

(c) If the statement of objections may not be filed, the Commissioner shall inform the objector of the reasons.

(d) If objections to a regulation issued pursuant to the filing of a petition are filed by a person other than the petitioner, the Food and Drug Administration shall send a copy of the objections by certified mail to the petitioner at the address given in the petition. Petitioner shall have 2 weeks from the date of receipt by him of the objections to make written reply.

§ 121.56 *Public hearing; notice.* If the objections and statements filed by any person, when they are considered with the record in the proceeding (including any reply to the objections that the petitioner may have filed), show that the person filing the objections is adversely affected and that the grounds stated in support of the objections are reasonable, and a public hearing on the objections is requested, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place where the hearing will be held, specify the time within which appearances must be filed, and specify the time (not earlier than 30 days after the date of publication of the notice in the FEDERAL REGISTER) when the hearing will commence. The hearing shall convene at the place and time announced in the notice, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing. Included in such notice shall be a statement indicating whether the regulation to which objection was taken shall be stayed pending the outcome of the hearing.

§ 121.57 *Presiding officer.* The hearing shall be conducted by a presiding officer, who shall be a hearing examiner appointed as provided in the Administrative Procedure Act (sec. 7, 60 Stat. 237, as amended; 5 U. S. C. 1007 et seq.) and designated by the Commissioner for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings shall be conducted in an informal but orderly manner in accordance with the regulations in this part and the requirements of the Administrative Procedure Act. The presiding officer shall have the power to administer oaths and affirmations, to rule upon offers of proof and admissibility of evidence, to receive relevant evidence, to examine witnesses, to regulate the course of the hearing, to hold conferences for the simplification of the issues, and to dispose of procedural requests; but he shall not have power to decide any motion that involves final determination of the merits of the proceeding.

§ 121.58 *Parties; burden of proof; appearances.* At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of section 7 (c) of the Administrative Procedure Act, the proponent of the order sought, and accordingly shall have the burden of proof. Any interested person shall be given an opportunity to apear at the hearing, either in person or by his authorized representative, and to be heard with respect to matters relevant to the issues raised by the objections. Any interested person who desires to be heard at the hearing in person or through a representative shall, within the time specified in the notice of hearing, file with the presiding officer a written notice of appearance setting forth his name, address, and employment. If such person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the name, address, and employment of such person. Any per-

son or representative shall state with particularity in the notice of appearance his interest in the proceedings and shall set forth the specific provisions of the regulations concerning which objections have been made on which such person desires to be heard. The notice of appearance shall also set forth with particularity the position to be taken concerning the objections on which he wishes to be heard. No person shall be heard if he failed to file notice of his appearance within the time prescribed, in the absence of a clear showing of good cause why the notice of appearance was not filed. All present at the hearing shall conform to all reasonable standards of orderly and ethical conduct.

§ 121.59 *Request for stay of effectiveness of regulation pending a hearing.* When a hearing is requested under § 121.55, the request may also include a request for a stay of effectiveness of the order (§ 121.59), in whole or in part, which request shall include the reasons for the stay together with a showing that the stay involves no hazard to the public health.

§ 121.60 *Prehearing and other conferences.* (a) The presiding officer, on his own motion or on the motion of any party or his representative, may direct all parties or their representatives to appear at a specified time and place for a prehearing conference to consider:

(1) The simplification of the issues.

(2) The possibility of obtaining stipulations, admissions of facts, and documents.

(3) The limitation of the number of expert witnesses.

(4) The scheduling of witnesses to be called.

(5) The advance submission of all documentary evidence.

(6) Such other matters as may aid in the disposition of the proceeding.

The presiding officer shall make an order reciting the action taken at the conference, the agreements made by the parties or their representatives, and the scheduling of witnesses, and limiting the issues for hearing to those not disposed of by admissions or agreements. Such order shall control the subsequent course of the proceeding unless modified for good cause by subsequent order.

(b) The presiding officer may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening of the hearing.

§ 121.61 *Submission of documentary evidence in advance of hearing.* (a) All documentary evidence to be offered at the hearing shall be submitted to the presiding officer and to the interested parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The presiding officer, after consultation with the parties at a conference called in accordance with § 121.60 shall make an order specifying the time at which documentary evidence shall be submitted. He shall also specify in his order the time within which objection to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer upon notice to the other parties within the time specified by the presiding officer in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 121.62 *Excerpts from documentary evidence.* When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the presiding officer and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document should be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 121.63 *Submission and receipt of evidence.* (a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary to prevent undue prolongation of the hearing, the presiding officer may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The presiding officer shall admit only evidence which is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(e) The presiding officer shall file as an exhibit a copy of the FEDERAL REGISTER promulgating the regulation to which objections were taken and the objections that form the basis for the hearing. All documents constituting the record bearing on the point in controversy, and not entitled to protection under section 301 (j) of the act, accumulated up to the start of the hearing shall be open for inspection by interested persons during office hours in the office of the Hearing Clerk of the Department, Room 5440, 330 Independence Avenue SW., Washington 25, D. C.

(f) If any person objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

§ 121.64 *Transcript of the testimony.* Testimony given at a public hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, shall be received in evidence subject to the Administrative Procedure Act (sec. 7 (c), 60 Stat. 238; 5 U. S. C. 1008 (c)). Exhibits shall, if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the presiding officer shall exercise his discretion in determining whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the presiding officer. Where the testimony of a witness refers to a statute, or to a report or document, the presiding officer shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the presiding officer.

§ 121.65 *Oral and written arguments.* (a) Unless the presiding officer issues an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The presiding officer shall announce at the hearing a reasonable period within which interested persons may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or properly identified exhibits where such evidence occurs.

§ 121.66 *Indexing of record.* (a) Whenever it appears to the presiding officer that the record of hearing will be of such length that an index to the record will permit a more orderly analysis of the evidence and reduce delay, the presiding officer shall require counsel for the parties to prepare a daily topical index, which will be available to the presiding officer and all parties. Preparation of such an index shall be apportioned among all counsel present in such manner as appears just and proper in the circumstances.

(b) The index shall include each topic of testimony upon which evidence is taken, the name of each witness testifying upon the topic, the page of the record at which each portion of his testimony appeared, and the number of each exhibit relating to the topic. The index shall also contain the name of each witness, followed by the topics upon which he testified and the page of the record at which such testimony appears.

§ 121.67 *Certification of record.* At the close of the hearing, the presiding officer shall afford interested persons a short time (not longer than 1 week, except in unusual cases) in which to point out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony, and he shall certify the transcript of testimony and the exhibits to the Commissioner.

§ 121.68 *Filing the record of the hearing.* As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the Hearing Clerk. The record shall include the transcript of the testimony, all exhibits, and any written arguments that may have been filed.

§ 121.69 *Copies of the record of the hearing.* The Department will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the record of the hearing or of any part thereof shall be entitled to the same upon payment of the costs thereof.

§ 121.70 *Proposed order after public hearing.* As soon as practicable after the time for filing written arguments has ended, the Commissioner shall prepare and cause to be published in the FEDERAL REGISTER a proposed order which shall set forth in detail the findings of fact and conclusions, and recommend decision on the objections that were the subject of the hearing and tentative regulations. The proposed order shall specify a reasonable time, ordinarily not to exceed 30 days, within which any interested person may file exceptions. The exceptions shall point out with particularity the alleged errors in said proposed order and shall contain a specific reference to the pages of the transcript of the testimony or to the exhibits on which each exception is based. Such exceptions may be accompanied by a memorandum or brief.

§ 121.71 *Final order after public hearing.* As soon as practicable after the time for filing exceptions has passed, the record and the exceptions shall be presented to the Secretary and he shall cause to be published in the FEDERAL REGISTER his final order promulgating the regulation, which shall specify the date on which the order shall take effect.

§ 121.72 *Adoption of regulation on initiative of Commissioner.* (a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall, after publication of the notice, proceed as provided in § 121.51.

§ 121.73 *Judicial review.* The Commissioner hereby designates the Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare as the officer upon whom copy of petition for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the order of the Secretary of Health, Education, and Welfare is based. The transcript and record shall be certified by the Secretary.

§ 121.74 *Procedure for amending and repealing tolerances or exemptions from tolerances.* (a) The Commissioner on his own initiative, or on request from an interested person furnishing reasonable grounds therefor, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exemption for such additive. Requests for such amendment or repeal shall be made in writing.

(b) "Reasonable grounds" shall include an explanation showing wherein the person has a substantial interest in such regulation and an assertion of facts (supported by data if available) showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data should be furnished in the form specified in § 121.51 for submitting petitions.

(c) The notice announcing the proposal to amend or repeal a regulation shall show whether the proposal was made on the initiative of the Commissioner or at the request of an interested person, naming such person. From this point, the proceedings shall be the same as prescribed by the regulations in this part and by section 409 (b) of the act, for the issuance of a regulation.

§§ 121.75–121.99 [Reserved.]

SUBPART B—EXEMPTION OF CERTAIN FOOD ADDITIVES FROM THE REQUIREMENT OF TOLERANCES

§ 121.100 *Substances that are generally recognized as safe.* It is impractical to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. In addition, the following lists include some substances that, when used for the purposes indicated, in accordance with good food manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

BUFFERS AND NEUTRALIZING AGENTS

Acetic acid.
Aluminum ammonium sulfate.
Aluminum sodium sulfate.
Aluminum potassium sulfate.
Ammonium bicarbonate.
Ammonium carbonate.
Ammonium hydroxide.
Ammonium phosphate (mono- and dibasic-).
Calcium carbonate.
Calcium chloride.
Calcium citrate.
Calcium gluconate.
Calcium hydroxide.
Calcium lactate.
Calcium oxide.
Calcium phosphate.
Citric acid.
Lactic acid.
Linoleic acid.
Magnesium carbonate.
Magnesium oxide.
Oleic acid.
Potassium acid tartrate.
Potassium bicarbonate.
Potassium carbonate.
Potassium citrate.
Potassium hydroxide.
Sodium acetate.
Sodium acid pyrophosphate.
Sodium aluminum phosphate.
Sodium bicarbonate.
Sodium carbonate.
Sodium citrate.
Sodium hydroxide.
Sodium phosphate (mono-, di-, tri-).
Sodium potassium tartrate.
Sodium sesquicarbonate.
Sulfuric acid.
Tartaric acid.

COLORS

Caramel.
Carbon black.
Charcoal.
Titanium dioxide.
Ultramarine blue.

PRESERVATIVES

SEQUESTRANTS

Calcium acetate.
Calcium chloride.
Calcium citrate.
Calcium diacetate.
Calcium gluconate.
Calcium hexametaphosphate.
Calcium phytate.
Citric acid.
Dipotassium phosphate.
Disodium phosphate.
Monocalcium acid phosphate.
Monoisopropyl citrate.
Potassium citrate.
Sodium acid phosphate.
Sodium citrate.
Sodium diacetate.
Sodium gluconate.
Sodium hexametaphosphate.
Sodium metaphosphate.
Sodium phosphate (mono-, di-, tribasic-).
Sodium potassium tartrate.
Sodium pyrophosphate.
Sodium tartrate.
Sodium tetrapyrophosphate.
Sodium tripolyphosphate.
Tartaric acid.

ANTIMYCOTICS

Calcium propionate.
Potassium sorbate.
Propionic acid.
Sodium propionate.
Sodium sorbate.
Sorbic acid.

ANTIOXIDANTS

Ascorbic acid.
Ascorbyl palmitate.
Calcium ascorbate.
Erythorbic acid.
Sodium ascorbate.
Tocopherols.

GENERAL

Acetic acid.
Citric acid.
Phosphoric acid.
Sorbitol.

MISCELLANEOUS

Aluminum sodium sulfate.
Aluminum sulfate.
Butane.
Calcium phosphate, tribasic.
Carbon dioxide.
Carnauba wax.
Glycerin.
Glycerol monostearate.
Helium.
Magnesium carbonate.
Magnesium hydroxide.
Monoammonium glutamate.
Nitrogen.
Papain.
Propane.
Propylene glycol.
Triacetin (glyceryl triacetate).
Tricalcium phosphate.
Sodium carbonate.
Sodium phosphate.
Sodium polyphosphate.

NONNUTRITIVE SWEETENERS

Calcium cyclohexyl sulfamate.
Calcium saccharin.
Saccharin.
Sodium cyclohexyl sulfamate.
Sodium saccharin.

NUTRIENTS

Ascorbic acid.
Calcium carbonate.
Calcium oxide.
Calcium panthothenate.
Calcium phosphate (mono-, di-, tribasic).
Calcium sulfate.
Carotene.
Ferric phosphate.
Ferric pyrophosphate.
Ferric sodium pyrophosphate.
Ferrous sulfate.
Iron, reduced.
l-lysine monohydrochloride.
Niacin.
Niacinamide.
D-Pantothenyl alcohol.
Potassium chloride.
Pyridoxine hydrochloride.
Riboflavin.
Riboflavin-5-phosphate.
Sodium pantothenate.
Sodium phosphate (mono-, di-, tribasic).
Thiamine hydrochloride.
Thiamine mononitrate.
Tocopherols.
α-Tocopherol acetate.
Vitamin A.
Vitamin A acetate.
Vitamin A palmitate.
Vitamin B_{12}.
Vitamin D_2.
Vitamin D_3.

STABILIZERS

Agar-agar.
Carob bean.
Carrageen.
Guar gum.

EMULSIFYING AGENTS

Acetyl tartaric acid esters of mono- and diglycerides, except lauric.
Mono- and diglycerides, except lauric.
Monosodium phosphate derivatives of mono- and diglycerides, except lauric.
Propylene glycol.

Product	Tolerance	Uses
MISCELLANEOUS		
Aluminum calcium silicate	2 percent	Table salt.
Calcium silicate	5 percent	As an anticaking agent in baking powder.
Calcium silicate	2 percent	As an anticaking agent in table salt.
Caffeine	½ to ½ grain in 6-ounce bottles of cola drinks.	In cola drinks.
Ethyl formate	15 parts per million	When used as fumigant for cashew nuts.
Magnesium silicate	2 percent	Table salt; anticaking agent.
Ox Bile Extract U. S. P. (solids)	0.01 percent	Egg whites.
Taurocholic acid (or its sodium salt)	do	Do.
Tricalcium silicate	2 percent	As an anticaking agent in table salt.
Triethyl citrate	0.25 percent	Egg whites.
NUTRIENTS		
Copper gluconate	0.005 percent	In any food.
Cuprous iodide	0.01 percent	Used in table salt as source of dietary iodine.
Potassium iodide	do	Do.
PRESERVATIVES		
ANTIMYCOTICS		
Caprylic acid		Antimycotic in cheese wraps.
Potassium bisulfite		Not in meats or in foods recognizable as a source of vitamin B.
Potassium metabisulfite		Do.
Sodium benzoate	0.1 percent	No special use specified.
Sodium bisulfite		Not in meats or in foods recognizable as a source of vitamin B.
Sodium metabisulfite		Do.
Sodium sulfite		Do.
ANTIOXIDANTS		
Benzoic acid	0.1 percent	No special use specified.
Butylated hydroxytoluene	0.02 percent	Edible fats and oils.
Butylated hydroxyanisole	do	Do.
Dilauryl thiodipropionate	do	Do.
Gum guaiac	0.1 percent	Do.
Nordihydroguaiaretic acid	0.02 percent	Do.
Propyl gallate	do	Do.
Thiodipropionic acid	do	Do.
GENERAL		
Sulfur dioxide		Not in meats or in foods recognizable as a source of vitamin B.
SEQUESTRANTS		
Isopropyl citrate	0.02 percent	No special use specified.
Sodium thiosulfate	0.1 percent	Salt.
Stearyl citrate	0.15 percent	No special use specified.
STABILIZERS		
Magnesium stearate		As migratory substance; use in manufacturing plastic film in wrapping foods.
SURFACTANTS		
Cholic acid	0.01 percent	Egg white.
Desoxycholic acid	do	Do.
Glycocholic acid	do	Do.

Dated: December 3, 1958.

[SEAL]

GEO. P. LARRICK,
Commissioner of Food and Drugs.

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